

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

ARTHUR, M. et al.

Serial No. 10/650,074

Filed: August 28, 2003

Title: TREATMENT FOR LIVER DISEASE

Atty Dkt. 117-473
C# M#

Examiner:

Date: March 29, 2005

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

 Correspondence Address Indication Form Attached.**Fees are attached as calculated below:**

Total effective claims after amendment	0	minus highest number	
previously paid for	20	(at least 20) =	0 x \$50.00
			\$0.00 (1202)/\$0.00 (2202) \$
Independent claims after amendment	0	minus highest number	
previously paid for	3	(at least 3) =	0 x \$200.00
			\$0.00 (1201)/\$0.00 (2201) \$

If proper multiple dependent claims now added for first time, (ignore improper); add
\$360.00 (1051)/\$180.00 (2051) \$

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s)

One Month Extension	\$120.00 (1251)/\$60.00 (2251)
Two Month Extensions	\$450.00 (1252)/\$225.00 (2252)
Three Month Extensions	\$1020.00 (1253)/\$510.00 (2253)
Four Month Extensions	\$1590.00 (1254)/\$795.00 (2254) \$

Terminal disclaimer enclosed, add
\$130.00 (1814)/ \$65.00 (2814) \$

Applicant claims "small entity" status. Statement filed herewith

Rule 56 Information Disclosure Statement Filing Fee
\$180.00 (1806) \$

Assignment Recording Fee
\$40.00 (8021) \$

Other:
\$

TOTAL FEE ENCLOSED \$ 0.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of

Confirmation No. 7212

ARTHUR, M. et al.

Atty. Ref.: 117-473

Serial No. 10/650,074

Group:

Filed: August 28, 2003

Examiner:

For: TREATMENT FOR LIVER DISEASE

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 29, 2005

Sir:

INFORMATION DISCLOSURE STATEMENT

1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits] N/C
- 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)] N/C
- 2 .(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)] \$180.00
3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith.

ARTHUR, M. et al.
Serial No. 10/650,074
March 29, 2005

This paper is submitted in accordance with:

- 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
 - a) The required Statement made in item 8 below; or
 - b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
 - a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
 - b) The required Statement is stated in item 8 below.
- 8. Statement under 37 CFR 1.97(e)
 - a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
 - b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

ARTHUR, M. et al.
Serial No. 10/650,074
March 29, 2005

Respectfully submitted,
NIXON & VANDERHYE P.C.

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INFORMATION DISCLOSURE CITATION		ATTY. DOCKET NO.	SERIAL NO.
		117-473	10/650,074
APPLICANT		MAR 29 2005 PATENT & TRADEMARK OFFICE U.S. DEPARTMENT OF COMMERCE	
(Use several sheets if necessary)		FILING DATE	GROUP
ARTHUR, M. et al			

(Use several sheets if necessary)

FILING DATE

SERIAL NO.

10/650,074

ARTHUR

GROUP

August 28, 2003

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

TRANSLATION

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Hadengue et al, "Beneficial Hemodynamic Effects of Ketanserin in Patients with Cirrhosis: Possible Role of Serotonergic Mechanisms in Portal Hypertension", <i>Hepatology</i> 7(4):644-647 (1987)
	Lebrec, D., "Portal Hypertension: Serotonin and Pathogenesis", <i>Cardiovascular Drugs and Therapy</i> 4:33-35 (1990)
	Pomier-Layrargues et al, "Combined Treatment of Portal Hypertension with Ritanserin and Propranolol in Conscious and Unrestrained Cirrhotic Rats", <i>Hepatology</i> 15:878-882 (1992)
	Wright et al, "Gliotoxin Initiates the Apoptosis of Rat and Human Hepatic Stellate Cells – A Mechanism for Modulating the Progression and Resolution of Liver Fibrosis", <i>Hepatology</i> 34(4):340A (2001) – AASLD Abstract No. 671 – XP009017657
	Wright et al, "Gliotoxin Stimulates the Apoptosis of Human and Rat Stellate Cells and Enhances the Resolution of Liver Fibrosis in Rats", <i>Gastroenterology</i> 121(3):685-698 (2001)
	Dekel et al, "Gliotoxin Ameliorates Development of Fibrosis and Cirrhosis in a Thioacetamide Rat Model", <i>Hepatology</i> 34(4):516A (2001) – AASLD Abstract No. 1377 – XP009022978
	Wright et al, "Gliotoxin stimulates apoptosis in cultured rat hepatic stellate cells", 30:98 (1999) (EASL Abstract P/C04/011) – Abstract, XP009022977
	Dekel et al, "Gliotoxin Ameliorates Development of Fibrosis and Cirrhosis in a Thioacetamide Rat Model", <i>Digestive Diseases and Sciences</i> 48(8):1642- 1647 (2003)
	Matsui et al, "Protective effect of sulfasalazine on hepatic ischemia-reperfusion injury in rats", <i>Japanese Journal of Pharmacology</i> 88:104P (2002) – Abstract, XP009030945
	Oakley et al, "Sulfasalazine Inhibits NFkB Activity and Induces Apoptosis of Rat Hepatic Stellate Cells", <i>Hepatology</i> 36(4):486A (2002) – Abstract, XP009030944
	Alcolado et al, "Pathogenesis of liver fibrosis", <i>Clinical Science</i> 92:103-112 (1997)

***Examiner**

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

INFORMATION DISCLOSURE		ATTY. DOCKET NO.	SERIAL NO.			
CITATION		117-473	10/650,074			
		APPLICANT				
		ARTHUR, M. et al.				
(Use several sheets if necessary)		FILING DATE	GROUP			
		August 28, 2003				
U.S. PATENT DOCUMENTS						
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)						
	Elsharkawy et al, "Persistent Activation of Nuclear Factor- κ B in Cultured Rat Hepatic Stellate Cells Involves the Induction of Potentially Novel Rel-Like Factors and Prolonged Changes in the Expression of I κ B Family Proteins", Hepatology 30(3):761-769 (1999)					
	Friedman, Scott L., "The Cellular Basis of Hepatic Fibrosis", The New England Journal of Medicine 328:1828-1835 (1993)					
	Friedman, Scott L., "Molecular Regulation of Hepatic Fibrosis, an Integrated Cellular Response to Tissue Injury", The Journal of Biological Chemistry 274(4):2247-2250 (2000)					
	Milani et al, "In Situ Hybridization for Procollagen Types I, III and IV mRNA in Normal and Fibrotic Rat Liver: Evidence for Predominant Expression in Nonparenchymal Liver Cells", Hepatology 10(1):84-92 (1989)					
	Trim et al, "Hepatic Stellate Cells Express the Low Affinity Nerve Growth Factor Receptor p75 and Undergo Apoptosis in Response to Nerve Growth Factor Stimulation", American Journal of Pathology 156(4):1235-1243 (2000)					
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	Calès, P., "Apoptosis and liver fibrosis: antifibrotic strategies", Biomed. & Pharmacother. 52:259-263 (1998)					
	Fischer et al, "Expression of the Peripheral-type Benzodiazepine Receptor and Apoptosis Induction in Hepatic Stellate Cells", Gastroenterology 120:1212-1226 (2001)					
	Gressner, Axel M., "The Up-and-Down of Hepatic Stellate Cells in Tissue Injury: Apoptosis Restores Cellular Homeostasis", Gastroenterology 120(5):1285-1288 (2001)					
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	Issa et al, "Apoptosis of hepatic stellate cells: involvement in resolution of biliary fibrosis and regulation by soluble growth factors", Gut 48(4):548-557 (2001)					
	Iwamoto et al, "Induction of apoptosis in rat hepatic stellate cells by disruption of integrin-mediated cell adhesion", J. Lab. Clin. Med. 134(1):83-89 (1999)					
	Lang et al, "Nuclear factor κ B in proliferation, activation, and apoptosis in rat hepatic stellate cells", Journal of Hepatology 33(1):49-58 (2000)					
	Murphy et al, "Inhibition of Apoptosis of Activated Hepatic Stellate Cells by Tissue Inhibitor of Metalloproteinase-1 Is Mediated via Effects on Matrix Metalloproteinase Inhibition", The Journal of Biological Chemistry 277(13):11069-11076 (2002)					
	Saile et al, "CD95/CD95L-Mediated Apoptosis of the Hepatic Stellate Cell", American Journal of Pathology 151(5):1265-1272 (1997)					
	Saile et al, "Transforming Growth Factor β and Tumor Necrosis Factor α Inhibit Both Apoptosis and Proliferation of Activated Rat Hepatic Stellate Cells", Hepatology 30(1):196-202 (1999)					
	Wright et al, "Gliotoxin Stimulates the Apoptosis of Rat and Human Hepatic Stellate Cells In Vitro", International Cells of the Hepatic Sinusoid 8:287-290 (2001)					
*Examiner		Date Considered				

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